K122861

Section 5: 510(k) Summary

DEC 0 7 2012

Device Information:

Category	Comments
Sponsor:	Ouroboros Medical, Inc. 47757 Fremont Blvd., Fremont, CA 94538
Correspondent Contact Information:	Shelley Trimm Consultant, Regulatory Affairs Ouroboros Medical, Inc. 47757 Fremont Blvd., Fremont, CA 94538 Tel: 510 933-3441 Fax: (866) 931-5422 Email:shelleytrimm@sbcglobal.net
Device Common Name:	Arthroscope and Accessories
Device Classification & Code:	Arthroscope: Class II, HRX Arthroscope Accessories: Class I, NBH
Device Classification Name:	21 CFR § 888.1100 Arthroscope and Accessories
Device Proprietary Name:	XTool™ MIS DISCECTOMY

Predicate Device Information:

Predicate Devices:	Arthrojet/SpineJet	Laparoscopic Disc Removal System
Predicate Device Manufacturers:	HydroCision	Blackstone Medical Inc.
K#s	041233	972768
Predicate Device Common Name:	Arthroscope and Accessories	Arthroscope and Accessories
Predicate Device Classification:	21 CFR § 888.1100	21 CFR § 888.1100
Predicate Device Classification & Code:	Arthroscope: Class II, HRX	Arthroscope: Class II, HRX

b. Date Summary Prepared

September 1, 2012

c. Description of Device

The XTool™ is an orthopedic manual hand held surgical instrument for use in performing discectomy in open and minimally invasive spine procedures. It is composed of an angled cutting head with serrated cutting edges and a distal guard, and a hollow shaft that connects the cutting head to the handle proximal. The handle has a port for connecting to standard hospital wall or pump suction. Two different diameter devices are specified to accommodate the range of disc heights for which a discectomy can be performed, with the smaller diameter for lower height discs, and the larger diameter for larger height disc. Two different tip angles are also specified to facilitate ipsilateral and contralateral disc removal. The finished assembly working length is 22 cm, Tip Angle is 15° or 40° and the cutter head diameter is either 5.2 mm or 6.3 mm.

d. Indications for Use

The XTool™ Device is indicated for spinal discectomy procedures for the cutting and removal of soft and hard tissue in open and minimally invasive spinal surgeries.

e. Comparison to Predicate Device

The Ouroboros Medical XTool™ MIS DISCECTOMY Device is substantially equivalent in intended use and technology to the currently marketed predicate devices the HydroCision Arthrojet/SpineJet handpiece (K041233) and the Blackstone Medical Inc. Laparoscopic Disc Removal System (K972768). Both the Application device and the predicate devices provide a means to cut soft tissue, remove cartilage, and aspirate tissue through a stainless steel tube in spinal surgeries. The Arthrojet/SpineJet handpiece has a cutting blade () at the tip and a tip orifice that draw tissue in to be aspirated through the collection tube. The XTool™ Device also has a cutting blade at the tip with a tip opening for drawing in tissue to be aspirated through a stainless steel tube. The Blackstone Laparoscopic Disc Removal System also has cutting edges around an opening at the tip that draws tissue in using suction to be aspirated through the stainless steel tube.

f. Summary of Supporting Data

Biocompatibility testing demonstrates that the device is in compliance with ISO 10993 for biocompatibility of the product.

Sterilization Validation has demonstrated that the device is in compliance with ISO 11137 standards for product sterility assurance.

Packaging Validation has demonstrated that the device is in compliance with ISO 11607-1.

Bench testing has demonstrated that the device is in compliance with the pertinent standards, the expectations of the medical community and the product labeling.

Simulated use cadaver testing demonstrated that the device can be used as intended in humans.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Ouroboros Medical
% Ms. Shelley Trimm
Consultant, Regulatory Affairs
47757 Fremont Boulevard
Fremont, California 94538

December 7, 2012

Re: K122861
Trade/Device Name: XTool™ MIS DISCECTOMY Device
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: October 18, 2012
Received: October 19, 2012

Dear Ms. Trimm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known): K122861

Device Name: XTool™ MIS DISCECTOMY Device

Indications For Use: The XTool™ Device is indicated for spinal discectomy procedures for the cutting and removal of soft and hard tissue in open and minimally invasive spinal surgeries.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)_____
Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden
2012.12.03 11:56:08 -05'00'

(Division Sign-off)
Division of Surgical Devices
510(k) Number_____K122861____